Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Ostrovit Sodium Butyrate supplementation on intestinal permeability and microbiota, anthropometric indices, complication and mortalility rate in children candidates for allogeneic hematopoietic stem cell transplantation: A randomized, double-blind clinical trial

Protocol summary

Study aim
the effect of sodium butyrate struvite supplementation on intestinal permeability and microbiota, anthropometric indices, complications and mortality after transplantation in children undergoing allogeneic hematopoietic stem cell transplantation

Design
Patients will be randomly assigned to either the intervention or control group using a randomized block design based on age and BMI-Zscore. Depending on the group they are in, patients will receive one 600 mg sodium struvite butyrate capsule daily or placebo for 12 weeks.

Settings and conduct
Children aged 2-18 years HSCT were selected and stool samples were collected .fasting blood was taken from the participants serum was separated and measured to measure citrulline and zenulin.the relevant bottles were coded as A and B by someone other than the researcher to ensure that the researcher and the patients were unaware of the type of supplements received by each group.

Participants/Inclusion and exclusion criteria
Inclusion criteria 1- Children between the ages of 2-18 years with hematological malignancies who are candidates for allogeneic hematopoietic stem cell transplantation and referred to the Transplant Center of the Children's Medical Center Hospital Exclusion criteria 1- Having other chronic diseases 2- Weekly consumption of probiotic supplements during the pas 3- Patients who are hospitalized at the beginning of the study. 4- Being on a diet or any specific changes in diet during the past three months

Intervention groups
Children between the ages of 2-18 years with hematological malignancies undergoing allogeneic hematopoietic stem cell transplantation

Main outcome variables
Bacterial phylum Citrulline Zenoline aGVHD Severity of gastrointestinal symptoms Number of hospitalizations Duration of hospitalization Weight Height BMI-Zscore Body fat mass Body muscle mass Muscle upper arm circumference (MUAC)

General information

Reason for update

Acronym
HSCT

IRCT registration information
IRCT registration number: **IRCT20260527069548N1**
Registration date: **2026-08-27, 1405/06/05**
Registration timing: **prospective**

Last update: **2026-08-27, 1405/06/05**
Update count: **0**

Registration date
2026-08-27, 1405/06/05

Registrant information

Name
Nazgol Bahreini

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 938 282 0489

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-10-23, 1405/08/01
Expected recruitment end date
2027-09-23, 1406/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Ostrovit Sodium Butyrate supplementation on intestinal permeability and microbiota, anthropometric indices, complication and mortalility rate in children candidates for allogeneic hematopoietic stem cell transplantation: A randomized, double-blind clinical trial

Public title
The effect of Ostrovit Sodium Butyrate supplementation in children candidates for allogeneic hematopoietic stem cell transplantation
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
1- Children between the ages of 2-18 years with hematological malignancies who are candidates for allogeneic hematopoietic stem cell transplantation and refer to the Transplant Center of the Children's Medical Center Hospital.
Exclusion criteria:
Having other chronic diseases (chronic intestinal inflammation, liver or kidney failure, celiac disease, etc.) Weekly intake of probiotic supplements during the past three months Patients who were hospitalized at the start of the study. Being on a diet or any specific dietary changes within the past three months
Age
From **2 years** old to **18 years** old
Gender
Both

Phase
1
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly assigned to one of two intervention and control groups using a randomized block design, in which patients are classified according to age and BMI-Zscore (Stratified Randomized Block Design).
Blinding (investigator's opinion)
Double blinded
Blinding description
In order to conduct this study in a double-blind manner, at the beginning of the study, the relevant set of bottles was coded as A and B by someone other than the researcher to ensure that the researcher and patients were unaware of the type of supplements received by each group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Ahvaz University of Medical Sciences
Street address
Ahvaz - Medical Sciences Boulevard - Jundishapur Medical Sciences
City
ahvaz
Province
Khouzestan
Postal code
6135715794
Approval date
2026-04-25, 1405/02/05
Ethics committee reference number
IR.AJUMS.REC.1405.031

Health conditions studied

1

Description of health condition studied
Children undergoing allogeneic hematopoietic stem cell transplantation
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Firmicutes, Bacteroidetes,Proteobacteria
Timepoint
Before the start of the intervention and three months after the intervention
Method of measurement
1 gram of each stool sample will be selected for

extraction. Molecular analysis will be performed using RT-qPCR (real-time polymerase chain reaction) using the Light Cycler 480 system.

2

Description
Citrulline
Timepoint
Before the start of the intervention and three months after the intervention
Method of measurement
HPLC method

3

Description
Zenolin
Timepoint
Before the start of the intervention and three months after the intervention
Method of measurement
Measurement by kit

4

Description
Severity of aGVHD
Timepoint
Before the start of the intervention and three months after the intervention
Method of measurement
aGVHD will be reviewed and recorded based on international standard criteria including clinical grading according to the GVHD grading index system, such as the Glucksberg or NIH consensus criteria, after study by the consultant professor and pediatric oncology specialist (Dr. Hamidieh and Dr. Behfar).

5

Description
Severity of digestive symptoms (bloating, pain, abdominal distension, diarrhea, constipation)
Timepoint
Before the start of the intervention and three months after the intervention
Method of measurement
By questionnaire

6

Description
Number of hospitalizations
Timepoint
Before the start of the intervention and three months after the intervention
Method of measurement
By questionnaire

7

Description
Length of hospital stay (days)
Timepoint
Before the start of the intervention and three months after the intervention
Method of measurement
By questionnaire

8

Description
Weight
Timepoint
Before the start of the intervention and three months after the intervention
Method of measurement
Via digital scale

9

Description
Height
Timepoint
Before the start of the intervention and three months after the intervention
Method of measurement
Wall-mounted thermometer

10

Description
BMI-Zscore
Timepoint
Before the start of the intervention and three months after the intervention
Method of measurement
CDC or WHO growth charts

11

Description
Body fat mass
Timepoint
Before the start of the intervention and three months after the intervention
Method of measurement
Bioelectrical Impedance Analysis

12

Description
Body muscle mass
Timepoint
Before the start of the intervention and three months after the intervention
Method of measurement
Bioelectrical Impedance Analysis

13

Description
Upper arm circumference (MUAC)
Timepoint
Before the start of the intervention and three months

after the intervention

Method of measurement

Tape measure

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Eligible participants will be randomly assigned to either the intervention or control group after day 15 following allogeneic hematopoietic stem cell transplantation. The intervention will be administered for 12 weeks.Participants in the intervention group will receive one capsule containing 600 mg of sodium butyrate orally once daily. The investigational supplement is a plant-based microencapsulated/enteric-coated formulation manufactured by a company located in Poland. Each capsule contains 600 mg of sodium butyrate, corresponding to 180 mg of butyric acid. Hydroxypropyl methylcellulose (HPMC) is used as an excipient/filler. The formulation is designed to protect the active ingredient from the acidic gastric environment and facilitate its release in the lower gastrointestinal tract. The supplement will be administered orally once daily with an adequate amount of water, according to the study instructions. Each participant will receive the intervention for 12 weeks, equivalent to 84 days. The capsules will be dispensed in containers containing 30 capsules. A total of 90 capsules will be provided in three separate containers to cover the entire intervention period. Adherence will be assessed by counting the remaining capsules. Participants who consume less than 90% of the prescribed capsules will be excluded from the study analysis. To maintain blinding, bottles containing the active supplement and placebo will be coded as A and B by an individual who is independent of the research team before the initiation of the study. The allocation codes will remain concealed from both the investigators and participants until completion of data collection and analysis. Randomization will be performed using a stratified randomized block design, with stratification according to age and BMI

Category

Treatment - Drugs

2

Description

Control group: Participants in the control group will receive one placebo capsule orally once daily for 12 weeks. The placebo will contain starch and will be manufactured by Takgene Company, Iran. The placebo capsules will be identical to the sodium butyrate capsules in terms of appearance, color, shape, odor, and packaging.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Children's Medical Hospital

Full name of responsible person

Dr. Seyed Ahmad Hosseini

Street address

Tehran - End of Keshavarz Boulevard - Gharib Street - Children's Hospital, Children's Medical Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr. Ahmad Hosseini
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Biochemistry
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Other areas of specialty/work
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Email
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
After the study is completed, the protocol and results will be published in the form of an article.
When the data will become available and for how long
One year after the start of the study
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
If recognized with the protocol in line with diagnostic and therapeutic goals in the field of children
From where data/document is obtainable
Dr. Ahmad Hosseini's email
What processes are involved for a request to access data/document
Given that the sampling period is estimated to be one year, data publication will be at least one year after the start of the study.
Comments